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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/756,018 11/25/96 SEED

B 00786/284002

EXAMINER

HM12/0321

CLARK & ELBING, LLP
176 FEDERAL STREET
BOSTON MA 02110-2214

FWO/D.T.G.

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

03/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/756,018

Applicant(s)

Seed et al.

Examiner

G. R. Ewoldt

Group Art Unit

1644

☒ Responsive to communication(s) filed on 3/6/00, 8/29/00, 12/11/00☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 10, 12-14, 24, and 25 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 10, 12-14, 24, and 25 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald R. Ewoldt, Group Art Unit 1644.

2. The request filed on 6/29/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/756,018 is acceptable and a CPA has been established. An action on the CPA follows.

3. Claims 10, 12-14, and 24-25 are pending.

4. In view of Applicant's amendments and responses, filed 3/06/00, 6/29/00, and 12/11/00, all previous rejections have been withdrawn.

5. The following are New Grounds for Rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10, 12-14, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

8. Claims 10, 12-14, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a purified nucleic acid consisting of SEQ ID NO:15 and SEQ ID NO:17,

does not reasonably provide enablement for:

a nucleic acid encoding a synthetic P-selectin ligand wherein said polypeptide contains a sialyl Le^x addition site and a tyrosine sulfation site, and wherein at least one of the sites is located at an amino acid position in said polypeptide which is different from its position in a naturally occurring P-selectin ligand.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure.

Regarding how to make the Invention, the specification discloses the making of a single nucleic acid encoding a polypeptide (consisting of (SEQ ID NO:15 and SEQ ID NO:17) comprising the claimed limitations. The other disclosed constructs comprise nucleic acids encoding either PSGL-1 fragments (which would not meet the claimed limitations of containing either a sialyl Le^x addition site or a tyrosine sulfation site located at an amino acid position different from its position in a naturally occurring P-selectin ligand) or prophetic sialyl Le^x-modified, tyrosine-sulfated antibodies which could, but have not, been made.

In Remarks filed 6/29/00, Applicant discloses that a P-selectin ligand with a sialyl Le^x addition site or a tyrosine sulfation site located at an amino acid position different from its position in a naturally occurring P-selectin ligand is a "surprising discovery." Applicant discloses that prior to the instant Invention the three dimensional structure of P-selectin ligands was considered to be "fixed", i.e., the sialyl Le^x addition site was required to be a certain distance from the tyrosine sulfation site. Given said disclosure of the prior art, any new P-selectin ligand not comprising said fixed three dimensional structure would be highly unpredictable and requiring of some demonstration (i.e., working examples) of an ability to function as a P-selectin ligand. The specification discloses only that the construct consisting of SEQ ID NO:15 and SEQ ID NO:17 was able to bind a P-selectin-Ig fusion protein in an *in vitro* culture system. No disclosure is made regarding the ability of any other asserted P-selectin ligand to actually bind P-selectin.

Regarding how to use the Invention, the specification provides just a single working example demonstrating the use of the single polypeptide consisting of SEQ ID NO:15 and SEQ ID NO:17 in an *in vitro* binding assay. The specification discloses however, that all intended uses of the polypeptides encoded by the claimed nucleic acids are *in vivo* therapeutic and diagnostic uses. Thus, *in vivo* enablement is required for the polypeptides encoded by the claimed nucleic acids. However, no demonstration (i.e., working examples) of any *in vivo* diagnosis, prevention, treatment, or cure of any disease or condition is disclosed. The

example demonstrating *in vitro* binding of a single synthetic construct to a single fusion protein P-selectin receptor is insufficient to demonstrate any particular *in vivo* diagnostic or therapeutic use. The specification essentially gives an invitation to experiment wherein the artisan is invited to find an *in vivo* use for the polypeptides encoded by the nucleic acids of the claimed invention. Said experimentation with such an unpredictable invention would be considered undue.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification regarding both how to both make and use the claimed invention, it would take undue trials and errors to practice the claimed invention.

It is noted that Applicant has made arguments, filed 3/6/00 and 6/29/00, to previous rejections under the first paragraph of 35 U.S.C. 112. However, said arguments are not relevant to the new rejections.

9. Claims 10, 12-14, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of the claimed "nucleic acid encoding a synthetic P-selectin ligand wherein said polypeptide contains a sialyl Le^x addition site and a tyrosine sulfation site, and wherein at least one of the sites is located at an amino acid position in said polypeptide which is different from its position in a naturally occurring P-selectin ligand." The specification discloses no limitation on the sites which might comprise either a "sialyl Le^x addition site" or a "tyrosine sulfation site". Absent any disclosed limitations, a "sialyl Le^x addition site" must be considered to be any amino acid capable of accepting either an O-linked or N-linked carbohydrate addition. Similarly, a "tyrosine sulfation site" must be considered to be any tyrosine. Thus the claims would therefore encompass an essentially unlimited number of nucleic acids encoding an essentially unlimited number of polypeptides. The specification, however, discloses just a single functional example. One of

skill in the art would therefore conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 10, 12-14, and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) the term "sialyl Le^x addition site" in claim 10 is vague and indefinite. It is unclear what constitutes said site other than any amino acid capable of accepting either an O-linked or N-linked carbohydrate addition,

B) the term "tyrosine sulfation site" in claim 10 is vague and indefinite. It is unclear what constitutes said site other than any tyrosine.

It is noted that Applicant has made arguments, filed 3/6/00 and 6/29/00, to previous rejections under the second paragraph of 35 U.S.C. 112. However, said arguments are not relevant to the new rejections.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Creation date: 09-08-2003
Indexing Officer: MDAVIS - MARQUETTA DAVIS
Team: OIPEBackFileIndexing
Dossier: 08756018

Legal Date: 09-24-2001

No.	Doccode	Number of pages
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Total number of pages: 14

Remarks:

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